commences (see § 40.63 (c)) for a pre-employment test is not deemed to have refused to test;

- (3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations; *Provided*, That an employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (see § 40.63 (c)) for a pre-employment test is not deemed to have refused to test:
- (4) In the case of a directly observed or monitored collection in a drug test, fail to permit the observation or monitoring of your provision of a specimen (see §§ 40.67(1) and 40.69(g));
- (5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see § 40.193(d)(2));
- (6) Fail or decline to take a second test the employer or collector has directed you to take;
- (7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under §40.193(d). In the case of a preemployment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment; or
- (8) Fail to cooperate with any part of the testing process (e.g., refuse to empty pockets when so directed by the collector, behave in a confrontational way that disrupts the collection process).
- (b) As an employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.
- (c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations.
- (d) As a collector or an MRO, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (including, in the case of the collector, printing the em-

ployee's name on Copy 2 of the CCF), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating a "shy bladder" condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.

- (1) As the collector, you must note the refusal in the "Remarks" line (Step 2), and sign and date the CCF.
- (2) As the MRO, you must note the refusal by checking the "refused to test because" box (Step 6) on Copy 2 of the CCF, and add the reason on the "Remarks" line. You must then sign and date the CCF.
- (e) As an employee, when you refuse to take a non-DOT test or to sign a non-DOT form, you have not refused to take a DOT test. There are no consequences under DOT agency regulations for refusing to take a non-DOT test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?

- (a) This section prescribes procedures for situations in which an employee does not provide a sufficient amount of urine to permit a drug test (*i.e.*, 45 mL of urine).
- (b) As the collector, you must do the following:
- (1) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see § 40.65(b) and (c)).
- (2) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of, the time at which the three-hour period begins and ends.
- (3) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site

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before the collection process is complete, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test.

- (4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER.
- (5) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.
- (c) As the DER, when the collector informs you that the employee has not provided a sufficient amount of urine (see paragraph (b)(4) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)
- (1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:
- (i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of urine to complete the test;
- (ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;
- (iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.
 - (2) [Reserved]
- (d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:
- (1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

- (i) Check "Test Cancelled" (Step 6) on the CCF; and
 - (ii) Sign and date the CCF.
- (2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:
- (i) Check "Refusal to test because" (Step 6) on the CCF and enter reason in the remarks line; and
 - (ii) Sign and date the CCF.
- (e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or dehydration.
- (f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.
- (g) If, as the referral physician making this evaluation in the case of a preemployment test, you determine that the employee's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of §40.195, where applicable.
- (h) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. You must report your determination to the DER in writing as soon as you make it.
- (i) As the employer, when you receive a report from the MRO indicating that

a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. The employee remains in the random testing pool.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.195 What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment follow-up or return-to-duty test because of a permanent or long-term medical condition?

- (a) This section concerns a situation in which an employee has a medical condition that precludes him or her from providing a sufficient specimen for a pre-employment follow-up or return-to-duty test and the condition involves a permanent or long-term disability. As the MRO in this situation, you must do the following:
- (1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the employee's physician and/or the physician who conducted the evaluation under §40.193(d).
- (2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.
- (3) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.
- (b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the employer as a negative test with written notations regarding results of both evaluation conducted under §40.193(d) and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist.
- (1) Check "Negative" (Step 6) on the CCF.
 - (2) Sign and date the CCF.

- (c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding results of both the conducted evaluation §40.193(d) and any further medical examination. This report must state that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test is needed for that purpose).
- (d) For purposes of this section, permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.
- (1) Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genito-urinary matters.
- (2) Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in paragraph (d)(1) of this section.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.197 What happens when an employer receives a report of a dilute specimen?

- (a) As the employer, if the MRO informs you that a positive drug test was dilute, you simply treat the test as a verified positive test. You must not direct the employee to take another test based on the fact that the specimen was dilute.
- (b) If the MRO informs you that a negative drug test was dilute, you may,